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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,230	10/23/2002	Jacques Dumas	03806.0531	9208

22852 7590 06/20/2005

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EXAMINER

CORDERO GARCIA, MARCELA M

ART UNIT PAPER NUMBER

1654

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,230

Applicant(s)

DUMAS ET AL.

Examiner

Marcela M Cordero Garcia

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/02</u> | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claims 1-17 are pending in the application.

Claims 1-17 are presented for examination on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arakawa et al. (Archives of Biochemistry and Biophysics, 1995) in view of Halenbeck et al. (US 5,861,150) and in further view of Hydrophobic Interaction Chromatography, Principles and Methods (Amersham Biosciences, 2000).

Arakawa et al. beneficially teach a process for purifying granulocyte colony-stimulating factor (G-CSF) from a biological sample, said process comprising:

a) reducing the volume of the biological sample containing G-CSF by chromatography to obtain a concentrated, and enriched fraction;

b) passing the concentrated fraction over hydroxyapatite under conditions where the G-CSF is weakly bound to obtain a concentrated, enriched fraction containing G-CSF; and

c) collecting the G-CSF (see, e.g., page 286, first paragraph).

Arakawa et al. do not specifically teach using hydrophobic interaction chromatography or desalted fraction in step a) nor do they teach a desalted fraction in step b).

Halenbeck et al. beneficially teach the use of a hydrophobic interaction chromatography to purify G-CSF from a biological sample.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust particular conventional working conditions within such a chromatographic separation method (e.g., using elution with water in a hydrophobic interaction resin in step a), using various ionic strength buffers in step b), or using a multi-stage process with ionic exchange chromatography, reversed phase gel filtration or affinity chromatography) based upon the overall beneficial teachings provided by Halenbeck et al. (See, e.g. column 7, lines 12-31) and Amersham Sciences (See, e.g., page 18, lines 7-11). These types of adjustments are deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the reference, especially in the absence of evidence to the contrary.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halenbeck et al. (US 4,929,700) in view of Hydrophobic Interaction Chromatography, Principles and Methods (Amersham Biosciences, 2000).

Halenbeck et al. beneficially teach a process for purifying granulocyte colony-stimulating factor (G-CSF) from a biological sample, said process comprising:

Step a) reducing the volumen of the biological sample containing G-CSF by hydrophobic interaction to obtain a concentrated, and enriched fraction; and

Step c) collecting the G-CSF (See, e.g., column 16, lines 1-15).

Halenbeck et al. do not specifically teach:

Step a) obtaining a desalted fraction of G-CSF

Step b) passing the concentrated fraction over hydroxyapatite under conditions where the G-CSF is weakly bound to obtain a concentrated, desalted, enriched fraction containing G-CSF (column 16, lines 1-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust particular conventional working conditions within such chromatographic separation method [e.g., utilizing elution with water in Step a), utilizing a tandem separation technique such as adsorption chromatography (such as hydroxyapatite) with various ionic strength buffers in Step b) or a multi-stage process with ion exchange chromatography, reversed phase gel filtration or affinity chromatography] based upon the overall beneficial teachings provided by Halenbeck et

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al. (See, e.g., column 7, lines 31-51) and Amersham Sciences (See, e.g., page 18, lines 7-11). These types of adjustments are deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the reference, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Marcela M Cordero Garcia, Ph.D.
Patent Examiner
Art Unit 1654

MMCG 06/05



CHRISTOPHER R. TATE
PRIMARY EXAMINER